This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

See reverse side for additional information.

Interagency Report Control No 0186-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NO. 43-R-0009 CUSTOMER NO. 1399

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

MIDWEST RESEARCH INST
425 VOLKER BLVD
KANSAS CITY, MO 64110
(816) 753-7600

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS *(sites)*

See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use APHIS FORM 7023A)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)*	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs	8	69	0	0	69
5. Cats	8	121	68	0	189
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	1	266	205	472
8. Rabbits	0	86	38	30	154
9. Non-Human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals					

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2) Each principal investigator has considered alternatives to painful procedures.

3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all the exceptions is attached to this annual report.** In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

NOV - 7 2007

4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional official)
I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

b6,b7c

DATE SIGNED 11/6/07

APHIS FORM 7023 (AUG 91)

(Replaces VS FORM 18-23 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

Column E Explanation

Facility Registration Number: 43-R-0009

Number of animals used in study: 212 (205 were category E)

Species: Hamsters

Explain the procedure producing pain and/or distress.

Propagation of strain 263K scrapie in hamsters provides reagent material utilized in prion clearance studies for FDA approved human therapeutics. Scrapie strain 263K is accepted as an animal model for human transmissible spongiform encephalopathy and was specifically selected for propagation in hamsters.

To propagate strain 263K hamster scrapie, hamsters were anesthetized and dosed (intracerebral) with 0.050 mL of 263K infected hamster brain homogenate. Once clinical symptoms have been observed twice over a period of at least 3 days (to ensure a high prion titer), then the animal is humanely euthanized and the brain harvested.

Provide scientific justification why pain and/or distress could not be relieved.

Hamster number 48 was found dead January 29, 2007. Clinical signs consistent with prion infection were observed on January 26, 2007. However, to ensure the scrapie prions reach a high titer in the hamster brains, it is necessary to observe clinical symptoms twice over a 3-5 day period. The rapid progression to death for this animal was unanticipated and inconsistent with the progression of typical prion disease. All of the other animals inoculated with prion homogenates did not develop clinical symptoms of prion disease until February 23, 2007.

The remaining animals were euthanized following two positive observations for clinical prion symptoms. It is necessary for the animals to exhibit clinical signs for more than one day to ensure sufficiently high titers of prion in the brain. Hamsters 1-115 were euthanized February 26, 2007 and hamsters 116-212 were euthanized March 1, 2007.

Column E Explanation

Facility Registration Number: 43-R-0009

Number of animals used in study: 68 (30 were category E)

Species: Rabbit

Explain the procedure producing pain and/or distress.

The National Institute of Allergy and Infectious Diseases (NIAID) has identified the rabbit as a potential animal model for tularemia infection and testing of vaccine candidates for prevention of tularemia. It has been shown to be susceptible to the pathogenic challenge organism, and a considerable amount of data supports the extrapolation of immunological results from this species to man. Since there is little relevant data regarding the virulence of the test article (a live virulent strain of *Francisella tularensis*) in rabbits, it is necessary to determine the MLD/LD50% to evaluate the virulence for use in vaccine efficacy and potency testing. Although OECD Guideline 425, Acute Oral Toxicity – Up-and-Down Procedure, is frequently recommended to replace the conventional LD50, this test is designed to test acute oral toxicity of chemicals and is easiest to apply to materials that produce death in less than 2 days. It is not practical for testing infectious agents, where delayed death (more than 5 days) may occur. The approach for a conventional LD50 is modified to use a minimum number of animals while providing statistically meaningful data. The number of animals used was reduced from five per sex per dose concentration to only three females per dose concentration for the preliminary study and four females per dose concentration for the definitive study. Moribundity with euthanasia is accepted as an endpoint, to minimize distress.

Animals are inoculated (single dose) with virulent organisms at one of three concentrations and observed for 21 days post dose. Those that become moribund are euthanized to prevent further suffering.

Provide scientific justification why pain and/or distress could not be relieved.

For a statistically valid test, the majority of the animals dosed with the test article become ill and a percentage of the animals must die. The LD50 concentration was determined using the Reed and Nuench calculation and mortality data. The use of analgesics or anesthetics would have prevented proper interpretation of signs and appropriate identification of moribund animals, thereby confounding test results.

Field Study

Facility Registration Number: 43-R-0009

Number of Animals used in Study: 27 (all 27 column C)

Species: Feline

The MRI-Kansas City IACUC approved a protocol for a field study using domestic house cats. The purpose of this study was to compare the ability of different types of fabric to collect cat dander. In this study, 27 house cats owned by MRI-Florida employee volunteers were used for the study. The owners brought a fabric sample home and rubbed them over the cat's body for a short period of time. The cats remained in their normal home environment at all times, and the fabric samples were brought back to MRI for analysis.